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UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF LOUISIANA, COMMONWEALTH OF MASSACHUSETTS, STATE OF NEVADA, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, STATE OF GEORGIA, STATE OF INDIANA, STATE OF MICHIGAN, STATE OF MONTANA, STATE OF NEW HAMPSHIRE, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF NEW JERSEY, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF WISCONSIN, STATE OF CONNECTICUT, STATE OF MINNESOTA, CITY OF CHICAGO ex rel. FRANK SMITH, Plaintiff, v. ASTELLAS PHARMA US, INC. Three Parkway North Deerfield, IL. 60015-2548, -and- ASTELLAS PHARMA INC. 2-3-11 Nihonbashi-Honcho, Chuo-ku Tokyo 103-8-411 Japan, -and-	:	C.A. NO. 10 - 999 **FILED *IN CAMERA* AND UNDER SEAL**

FILED
MAR 08 2010
MICHAEL E. KUNZ, Clerk
By_____ Dep. Clerk

HOFFMAN-LA ROCHE INC., :
340 Kingsland St
Nutley, NJ 07110, :

-and- :

ROCHE LABORATORIES INC., :
340 Kingsland St
Nutley, NJ 07110, :

-and- :

F. HOFFMAN-LA ROCHE LTD. :
100 Philips Parkway
Montvale, NJ 07645, :

-and- :

ROCHE HOLDING LTD. :
Grenzacherstrasse 124
Basel :
CH-40-70
Switzerland, :

Defendants. :

COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE *QUI TAM* PROVISIONS OF THE FALSE CLAIMS ACT AND SIMILAR STATE PROVISIONS

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and individual states and cities arising from Defendants Astellas Pharma US, Inc., Astellas Pharma Inc. (collectively referred to herein as "Astellas"), Hoffman-La Roche Inc., Roche Laboratories Inc., F. Hoffman-La Roche Ltd. and Roche Holding Ltd.'s (collectively referred to herein as "Roche") conduct in causing the filing of false claims to be presented to Medicare, Medicaid, TRICARE and other federally-funded government health care

programs (collectively, "Government Health Care Programs"). Both the Astellas and Roche entities will be collectively referred to herein as "Defendants."

2. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payment for certain health services provided to additional classes of certain individual health care patients pursuant to federal regulations.

3. The federal government enacted the Medicaid program in 1965 as a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through the Center for Medicare and Medicaid Services ("CMS"). See 42 U.S.C. §1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. See 42 U.S.C. §1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of "the total amount expended . . . as medical assistance under the State plan . . ." See 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as federal financial participation ("FFP").

4. TRICARE is the component agency of the U.S. Department of Defense that administers and supervises the health care program for certain military personnel and their dependents. TRICARE contracts with a fiscal intermediary that receives, adjudicates, processes and pays health care claims submitted to it by TRICARE beneficiaries or providers. The funds used to pay the TRICARE claims are federal government funds. In addition to Medicare,

Medicaid and TRICARE, the federal government also reimburses for the cost of prescription drugs under several other Government Health Care Programs, including the Railroad Retirement Medicare Program, the Federal Employee Health Benefit Plans, the Veterans Administration, the Indian Health Service and State Legal Immigrant Assistance Grants.

II. JURISDICTION AND VENUE

5. This *qui tam* claim arises under the provisions of the False Claims Act, 31 U.S.C. 3729, et seq. ("FCA"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and 31 U.S.C. §3732 which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730.

6. Personal jurisdiction and venue for this action are predicated on 31 U.S.C. 3732(a) which provides that "any action brought under 3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants, any one defendant can be found, resides, transacts business or in which any act prescribed by 3729 occurred." Defendants transact substantial business in the Eastern District of Pennsylvania.

7. This Court also has supplemental jurisdiction over the California, Delaware, District of Columbia, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, Tennessee, Texas, Virginia, Georgia, Indiana, Michigan, Montana, New Hampshire, New Mexico, New York, New Jersey, Oklahoma, Rhode Island, Wisconsin, Connecticut, Minnesota, and City of Chicago *qui tam* claims pursuant to 28 U.S.C. §1367 which provides that "in any civil action of which the district courts have original jurisdiction, the district court shall have supplemental jurisdiction over all claims that are so related to claims in action in such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution."

8. Under the FCA, this Complaint is to be filed *In Camera*, remain under seal for a period of at least sixty (60) days and shall not be served on the Defendant until the Court so orders. The government may elect to intervene and proceed with the action within sixty (60) days after it receives both the Complaint and the material evidence and information.

III. PARTIES

9. *Qui Tam* Plaintiff Frank Smith ("Relator") is a citizen and resident of the Commonwealth of Pennsylvania, and resides at 1813 Mifflin Street, Philadelphia, PA 19145. He brings this action on behalf of the United States of America and the states and cities referenced herein.

10. Relator has been employed with Astellas Pharma US, Inc. since February 2008 to the present as a sales representative for the drug Mycamine®, as well as other company products. As such, he has personal knowledge of Defendants' conduct and in particular, its illegal off-label marketing and pricing of the drug Mycamine to pediatric institutions and for pediatric use.

11. Relator brings this action based on his direct knowledge and also on information and belief. None of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. 3730(e)(4). Notwithstanding same, Relator is an original source of the facts alleged in this Complaint.

12. As a sales representative for Astellas, Relator has direct and independent information of the allegations in this Complaint.

13. Relator attended and continues to attend meetings and made and continues to make sales calls regarding the marketing of Mycamine to children's hospitals, including his largest account, Alfred I. duPont Hospital for Children ("duPont Hospital for Children"). As will

be described further below, Relator also worked with Roche sales representatives regarding the marketing of Mycamine until approximately April 2009.

14. Relator also has direct and independent knowledge regarding Mycamine's pricing plan which induces children's hospitals to add Mycamine to their formularies and to prescribe it off-label thereby allowing Astellas to gain exorbitant profits from sales to children's hospitals while circumventing FDA regulations regarding pediatric indications.

15. As required under the FCA, Relator will provide to the Attorney General of the United States, the United States Attorney for the Eastern District of Pennsylvania and the State Attorneys General identified in this Complaint, a statement of all material evidence and information related to the Complaint. This disclosure statement supports the existence of false claims made by Astellas, Roche and possibly others to the Government Health Care Programs.

16. Defendant Astellas Pharma US, Inc. is a U.S. affiliate of Tokyo-based Astellas Pharma Inc. Astellas Pharma US, Inc.'s principal place of business and North American headquarters is in Deerfield, Illinois.

17. Defendant Astellas Pharma Inc. is foreign corporation with its corporate headquarters in Toyko, Japan. Astellas Pharma Inc. was formed in 2005 after the Japanese pharmaceutical firms Yamanouchi Pharmaceutical and Fujisawa Pharmaceutical Company merged, thereby creating one of the largest pharmaceutical companies in Japan.

18. At all times relevant hereto, Astellas acted through its agents and employees, and the acts of Astellas agents and employees were within the scope of their agency and employment. The policies and practices alleged in this complaint were, on information and belief, established and/or ratified at the highest corporate levels of Astellas.

19. Defendant Hoffman-La Roche Inc. is a New Jersey corporation, and Defendant Roche Laboratories Inc., is a Delaware corporation, with their principal place of business located at 340 Kingsland Street, Nutley, New Jersey 07110.

20. Defendant, Roche Holding Ltd., a foreign corporation, is a joint-stock company with its registered office in Basel, Switzerland, whose purpose is to hold shared in companies that manufacture pharmaceutical and other products. Defendant, Roche Holding Ltd., is and was the parent corporation of Defendant, F. Hoffmann-La Roche Ltd., a foreign corporation, which also has its corporate headquarters in Basel, Switzerland. Defendants, Hoffman-La Roche Inc. and Roche Laboratories Inc., are wholly owned subsidiaries of Defendant, Roche Holding Ltd. and/or F. Hoffmann-La Roche Ltd.

21. From approximately 2005 until April 2009, Roche acted as an agent of Astellas by co-promoting Mycamine off-label through a co-promotion agreement with Astellas.

22. As an agent of Astellas by way of the Mycamine co-promotion agreement, Roche is jointly and severally liable for the illegal promotion, pricing and sales of Acellas' drug Mycamine during effective dates of the Mycamine co-promotion agreement.

23. Roche presents its sales and profits to the public on a unified worldwide basis. Roche present themselves as a highly integrated single entity, releasing one unified set of financial statements and representing itself as one unit. Roche does not differentiate by entity, but instead refer to internal divisions that cut across entity lines. Roche has one global e-mail system, one global standard operating procedures manual, and one global database regarding its pharmaceuticals.

IV. FACTUAL ALLEGATIONS

24. On information and belief, Astellas and Roche have embarked on a national sales program to aggressively market the antifungal drug, Mycamine, to children's hospitals and other pediatric prescribers presenting a increased risk of harm to children.

25. Mycamine was the first new product launched in the United States by Astellas.

26. From approximately May 2005 through April 2009, Roche co-promoted Mycamine with Astellas by way of a co-promotion agreement. Defendants entered into a co-promotion agreement in order to augment Astellas' hospital sales force in the promotion of Mycamine throughout the United States

27. Almost immediately after he became employed by Astellas in February 2008, Relator first learned that Astellas' and Roche's nationwide sales program was promoting Mycamine in a manner and to persons for whom the Food and Drug Administration ("FDA") had not approved its use.

28. Off-label marketing is a practice whereby a pharmaceutical company promotes a drug for the treatment of symptoms and conditions, other than those in its FDA approved indication.

29. A drug achieves an approved indication only after vigorous FDA review of tests and studies demonstrating the drug's safety and efficacy. Restrictions can also be placed on patient populations so that the use is limited to those for whom the drug is considered safe and effective.

30. A drug achieves an approved indication in a relevant pediatric subpopulation only after the FDA's strict review of data that are adequate to assess the safety and

effectiveness of the drug product for the claimed indications in the pediatric subpopulation, as well as data that supports the dosing and administration for each pediatric subpopulation.

31. Mycamine, an antifungal agent consisting of micafungin sodium that is administered by intravenous injection, is only approved by the FDA for the treatment of Candidemia, Acute Disseminated Candidiasis, *Candida* Peritonitis and Abscesses, Esophageal Candidiasis and the prophylaxis of *Candida* Infections in patients undergoing Hematopoietic Stem Cell Transplantation.

32. Mycamine is only approved for adult patients and does not contain a pediatric indication.

33. In March 2005, Mycamine was approved by the U.S. Food and Drug Administration ("FDA") for the prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation and the treatment of esophageal candidiasis.

34. On or about December 21, 2006, Astellas submitted a Supplemental New Drug Application ("sNDA") to the FDA seeking approval for the use of Mycamine for injection in the treatment of Candidemia and other *Candida* infections.

35. Upon information and belief, Astellas did not, either through its NDA or sNDA, seek FDA approval for the use of Mycamine in the pediatric subpopulation.

36. On or about January 22, 2008, the FDA approved Astellas' Supplemental New Drug Application ("sNDA") approving Mycamine for the treatment of patients with Candidemia, Acute Disseminated Candidiasis, *Candida* Peritonitis and Abscesses, in addition to its initial approval for the treatment of patients with Esophageal Candidiasis and the prophylaxis of *Candida* Infections in patients undergoing Hematopoietic Stem Cell Transplantation.

37. Mycamine has never been approved by the FDA for the pediatric population.

38. The safety and efficacy of Mycamine in pediatric patients has not been established in clinical studies, a fact which is set forth in Mycamine's prescribing information.

39. Mycamine is a member of a newer class of antifungal agents, the echinocandins, that inhibit an enzyme essential for fungal cell-wall synthesis and is fungicidal (lethal) for *Candida*. Clinical studies conducted by various entities indicate that users of the drug sometimes experience serious side effects including, but not limited to, hypersensitivity (anaphylaxis and anaphylactoid) reactions (including shock), acute intravascular hemolysis and hemoglobinuria, significant hemolysis and hemolytic anemia, significant hepatic dysfunction, hepatitis, and hepatic failure (liver failure), significant renal dysfunction or acute renal failure, hypokalemia (which could result in heart failure), hypertension, and hypotension.

40. Animal toxicology studies performed by Astellas during Mycamine's pre-clinical phase also show a significantly higher incidence of liver tumors in rats compared to control groups. Mycamine's competitors caspofungin (brand name Cancidas® manufactured by Merck & Co. Inc.) and Anidulafungin (brand name Eraxis® manufactured by Pfizer Inc.) do not carry the same risks.

41. While Mycamine is approved in the European Union (and Japan) for use in children less than 16 years of age, it is only approved for very limited indications, including the treatment of invasive candidiasis and prophylaxis of *Candida* infection in children undergoing allogeneic haematopoietic stem cell transplantation or children who are expected to have neutropenia for 10 days or more. The decision to permit use of Mycamine in the pediatric

population for these restricted uses takes into account the potential risk for the development of liver tumors.

42. For instance, the Scottish Medicines Consortium completed an assessment on Mycamine and published the following results:

> Indication
> - Treatment of invasive candidiasis in adults, elderly, and children (including neonates).
> - Treatment of oesophageal candidiasis in adult, elderly, and adolescent (≥16 years of age) patients for whom intravenous therapy is appropriate.
> - For prophylaxis of Candida infection in adults, elderly, and children (including neonates) undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia (absolute neutrophil count < 500 cells/μl) for 10 or more days.
>
> **The decision to use micafungin should take into account a potential risk for the development of liver tumours. Micafungin should therefore only be used if other antifungals are not appropriate.**

43. In the UK, Mycamine carries a black box warning that reads:

> In rats, long-term treatment with micafungin led to liver damage and subsequent liver tumours. The potential risk of developing liver tumours in humans in not known, and your doctor will assess the benefits and risks of Mycamine treatment before starting your medicine. Please tell your doctor if you have severe liver problems (e.g. liver failure or hepatitis) or have had abnormal liver function tests. During treatment your liver functions will be monitored more closely.

44. The European Medicines Agency also concluded that Mycamine carried additional risks and side effects in children such as: "(seen in between 1 and 10 children in 100) are thrombocytopenia (low blood platelet counts), tachycardia (rapid heart rate), hypertension

(high blood pressure), hypotension (low blood pressure), hepatomegaly (enlarged liver), acute renal failure (sudden kidney failure) and increased blood urea levels."

45. In the United States, Mycamine's prescribing information either downplays or fails to warn of the risk of liver damage and liver tumors, and carries no additional or special warnings for children since it is unapproved in the pediatric population. Mycamine's prescribing information carries no black box warning in the United States.

46. Astellas and Roche marketed and sold Mycamine to children's hospitals for all adult indications in the pediatric population without warning of the risk of liver tumors.

47. The risk of side-effects to children when ingesting pharmaceuticals like Mycamine increases many times with increased dosage.

48. According to information provided by Astellas to Relator, doctors are required to provide a higher dosage to Mycamine to children than adults due to a child's ability to metabolize the drug quicker, thereby causing additional risk and harm to children.

49. Defendants made a marketing decision to aggressively promote Mycamine to physicians practicing in adolescent medicine and other adolescent specialties and for prescription to children.

50. Defendants' decision to promote Mycamine for prescription to children without FDA approval for a pediatric subpopulation was done despite the health risks to children, and the lack of studies regarding the drug's safety and efficacy.

51. Astellas' own Mycamine training manuals provided to its sales force state that "the age of a patient can also effect metabolism of a drug and, therefore, increase the risk of adverse drug reactions. Infants and very young children are at high risk for adverse drug reactions because their capacity to metabolize drugs is not fully developed."

52. Astellas' own training manuals state that further studies are required to fully elucidate the safety and efficacy of Mycamine in pediatric and neonatal patients.

53. Despite its own admissions of the health risks involved, Astellas and its agent Roche engaged in a national marketing plan and aggressively marketed Mycamine to the pediatric population.

54. Cancidas, manufacturered by Merck & Co. Inc., is a direct competitor of Mycamine. Unlike Mycamine, Candidas is approved in pediatric patients (3months and older) for empirical therapy for: (a) presumed fungal infections in febrile, neutropenic patients; (b) treatment of candidemia and the following *Candida* infections: intra-abdominal abscesses, peritonitis and pleural space infections; (c) treatment of esophageal candidiasis; and (d) treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies (e.g. amphotericin B, lipid formulations of amphotericin B, itraconazole).

55. Particular pressure was placed on sales persons with children's hospitals in their sales territories (including duPont Hospital for Children in Wilmington, DE, The Children's Hospital of Philadelphia, and Saint Christopher's Hospital for Children) to market as Mycamine not only safe for children but superior to its counterpart Cancidas, even though Mycamine has no pediatric indication.

56. Defendants marketed Mycamine off-label by promoting the drug with pediatric subanalyses performed in various studies, including "Mycamine Versus Liposomal Amphotericin B for Pediatric Patients With Invasive Candidiasis, Substudy of a Randomized Double-Blind Trial," by F. Queirox-Telles, M.D., et al. (the "Micafungin-Liposomal Study"), as well as other Washington Legal Foundation ("WLF") Reprints concerning Mycamine and other antifungal agents.

57. Defendants instructed sales representatives to distribute pediatric studies like the Micafungin-Liposomal Study to children's hospitals in response to requests for (1) information on the treatment of candidiasis; (2) Mycamine comparative data; (3) first-line treatment of candidiasis with AmBisome; or (4) specific requests for the article, knowing that the distribution of this information to doctors at children's hospitals under the semblance that they were being distributed in response to "appropriate unsolicited requests" would result in significant off-label prescriptions of Mycamine.

58. Sales representatives were instructed to use the Micafungin-Liposomal Study to respond to dosing questions from pediatric oncologists and other doctors at pediatric hospitals, by turning the first page of the study over and using page 2 as the dosing standard for children. This was done even though Mycamine dosing in children has not been adequately studied or FDA-approved.

59. On or about March 27, 2009, Astellas sent a notice to its sales force suspending the use of certain WLF reprints in response to "unsolicited requests" from healthcare providers (the "March 2009 email"). The WLF studies listed in the email included studies referenced as MYC00392, 00325, and 00203, which were studies used by sales representatives to promote sales in pediatric accounts.

60. The March 2009 email from Astellas to its sales force is further evidence that Defendants were improperly using WLF reprints to promote Mycamine to pediatric hospitals.

61. Defendants engaged in a scheme to circumvent FDA regulations and strict testing requirements for a pediatric indication by aggressively marketing Mycamine to pediatric hospitals through use of the Academy of Managed Care Pharmacy Dossier ("AMCP Dossier")

for Mycamine. The AMCP Dossier was prepared by Astellas for provision of a formulary submission for Mycamine provided to pharmacist and physician managed care and hospital decision makers in formulary and coverage evaluations, and a budget impact calculator with default settings for unapproved indications and dosages of Mycamine.

62. A large portion of the AMCP Dossier for Mycamine is dedicated to pediatric use.

63. By providing children's hospitals with such low pricing based on 100% off-label promotion, and using pediatric studies to achieve this result, Astellas was able to evade FDA regulation and achieve record sales and profits for Mycamine without performing the necessary studies and obtaining FDA approval for a pediatric indication, placing children's lives in jeopardy.

64. Astellas and its Roche agents would advise children's hospitals that they would save hundreds of thousands of dollars through the use of its budget impact calculator that if Mycamine replaced its competitor Cancidas on the formulary, even through Candidas had a pediatric indication and Mycamine did not.

65. In order to obtain a substantial discount in excess of 45%, Defendants required children's hospitals to sign marketshare (exclusivity) contracts with Astellas. This required the hospital to use Mycamine at least 80% of the time and penalized the hospital through pricing if the hospital were noncompliant.

66. Astellas' sales representatives received monthly compliance reports regarding hospital accounts were directed to make sales calls on hospital pharmacists if Mycamine prescriptions fell below 80%. These accounts included children's hospitals.

67. One of the means by which Astellas and its agent Roche marketed or continues to market Mycamine is through the use of highly paid outside physicians known within the company as "thought leaders." These physicians received remuneration per appearance to speak with doctors and pharmacists about the merits of Mycamine in the pediatric population.

68. Specifically, Defendants sponsored Local Promotional Meetings whereby pediatric doctors like Ben Z. Katz, M.D., a Pediatric Infectious Disease doctor, and Allen Korenblit, M.D., a Pediatric Hematologist-Oncologist, promoted Mycamine to doctors for use in children and discussed, among other things, dosing in children.

69. Astellas', and presumably, Roche's, sales representatives also scheduled private meetings with outside paid physicians to discuss the safety and efficacy Mycamine in the pediatric population.

70. Federal laws and regulations government the Government Health Care Programs prohibit kickbacks or inducements paid to physicians and medical care providers. The Anti-Kickback statute provides that it is a felony to knowingly or willfully offer to pay any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person "to purchase, lease, order, or arrange for or recommend purchasing, leasing or ordering any good, facility, service or item for which payment may be made in while or in part under a Federal health care program." 42 U.S.C. §1320a-7b(b)(2).

71. As part of its nationwide program for Mycamine in which pediatric doctors were paid speakers, Defendants established a system of kickbacks to physicians who are prescribers of the drug or can substantially influence pediatric physician population.

72. These kickbacks are strictly illegal and have the effect of greatly increasing the amount of Mycamine prescriptions and, indirectly, the amount of money spent by the federal government for reimbursement of prescriptions covered by the Government Health Care Programs.

73. Payment of these kickbacks represents the inducement of federal payments through a pattern of fraudulent conduct and constitute false claims within the meaning of 31 U.S.C. §3729.

74. The Local Promotional Meetings and other speaker programs are or were sponsored by Defendants knowing in advance that the speakers will tout the use of Mycamine for use in children, an unapproved use by the FDA and federal regulation.

75. Defendants' sales force encouraged the promotion of Mycamine for FDA unapproved uses. Sales people receive sales credit for new landing accounts at children's hospitals and are encouraged to make strong sales pitches to children's hospitals since a large amount of Mycamine sales is to the pediatric population. Sales persons are required to use Astellas' Budgetary Impact Calculator to promote hospital savings when Mycamine is prescribed for off-label uses.

76. In Astellas' second quarter of the fiscal year 2008, Mycamine sales in North America totaled $20 million, and in the second quarter of the fiscal year 2009, Mycamine North American sales totaled $37 million, increasing 81%.

77. Upon information and belief, approximately 30-40% of Mycamine's sales are pediatric sales.

78. Astellas' increase in sales from 2008 to 2009 is due to, among other things, Defendants' improper use of the Micafungin-Liposomal Study, which was published in September 2008, to off-label promote to and land pediatric accounts.

79. Defendants embarked upon this course of unlawful conduct knowing it would lead to the submission of claims for Mycamine by Medicare and Medicaid-participating providers, when by statute these claims were not reimbursable and would not have been reimbursed by Government Health Care Programs has the truth about Defendants' illegal marketing practices been known.

80. Defendants knew and/or continue to know that off-label prescriptions for Mycamine were ineligible for reimbursement by the Government Health Care Programs and that this conduct and its other marketing activities would, in fact, cause numerous ineligible prescriptions to be submitted to the Government Health Care Programs, Thus, the doctors', hospitals' and pharmacists' participation in the submission of the false claims was foreseeable, as well as an intended consequence of Defendants' scheme.

81. Defendants' illegal encouragement and marketing of an off-label use (pediatric administration) for Mycamine resulted in a substantial increase in its prescriptions thereby causing the Government Health Care Programs to pay out more for prescriptions that are not eligible for payment. Defendants specifically intended for their off-label promotional campaigns to improperly increase the submissions of off-label prescriptions, including such prescriptions reimburse by the Government Health Care Programs.

82. All claims submitted for a drug when the drug was prescribed for an off-label use not only violates Government Health Care Program payment rules but also constitute a false claim under the federal FDA and the analogous laws of the States named in this Complaint.

Astellas and through its agent Roche, marketed Mycamine for use in children, an off-label use, in violation of the FDA and the analogous state statutes. Defendants' off-label marketing practices and other wrongful conduct knowingly caused doctors, hospitals and pharmacists to file false reimbursement requests in violation of the FCA, as well as place children's lives in danger.

COUNT I.

VIOLATION OF THE FALSE CLAIMS ACT, 31 U.S.C. § 3729

83. Relator repeats and realleges the foregoing paragraphs of this Complaint.

84. Astellas, from approximately March 2005 to the present, and Roche, from approximately March 2005 through April 2009, acted in reckless disregard or deliberate ignorance of the truth or falsity of the information they conveyed, caused the submission of false or fraudulent claims to be paid or approved by the Government in violation of 31 U.S.C. § 3729(a)(1) and (a)(2) through their off-label promotion of Mycamine.

85. Astellas, from approximately March 2005 to the present, and Roche, from approximately March 2005 through April 2009, in reckless disregard or deliberate ignorance of the truth or falsity of the information they conveyed, conspired with physicians, pharmacies and others to defraud the Government Health Care Programs by causing false or fraudulent claims for reimbursement to be paid or approved by the government in violation of 31 U.S.C. § 3729(a)(3).

86. Astellas and Roche have also violated 31 U.S.C. § 3729(a)(2) by causing the states to submit false claims to the United States Government in Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including Mycamine, were paid for in compliance with federal law. States submitted false claims to the Government Health

Care Programs because when Mycamine was prescribed off-label, it was not prescribed for a medically accepted indication, yet states sought reimbursement from the United States Government for all Mycamine expenditures

87. The United States, its fiscal intermediaries and state Medicaid programs, were unaware of Astellas' and Roche's off-label sales promotion or the falsity of the records, statements, claims and illegal kickbacks made by Defendants and as a result thereby have paid and continue to pay Government Health Care Programs' reimbursement that they would not otherwise have paid.

88. The United States has been damaged by the payment of false and fraudulent claims.

89. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the United States:

(1) Three times the amount of actual damages which the United States has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the United States;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to § 3730(d) of the FCA and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT II.

CALIFORNIA FALSE CLAIMS ACT

90. Relator repeats and realleges the foregoing paragraphs of this Complaint.

91. This is a qui tam action brought by Relator on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 et seq.

92. Cal. Gov't Code § 12651 (a) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
(3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
. . .
(8) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

93. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

94. Astellas and Roche furthermore violated Cal. Gov't Code § 12651 (a) and knowingly caused false claims to be made, used and presented to the State of California by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, Cal. Bus. & Prof. Code § 650-650,1 and Cal. Welf. & Inst. Code § 14107.2 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Health Care Programs.

95. The State of California, by and through the California Medicaid program and other state healthcare programs, and unaware of Astellas' and Roche's conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

96. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of California in connection with Astellas' and Roche's conduct. Compliance with applicable California statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of California.

97. Had the State of California known that false representations were made to children's hospitals and practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

98. As a result of Astellas' and Roche's violation of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

99. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of California:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $5000 and not more than $10,000 for each false claim which Defendant presented or caused to be presented to the State of California;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT III.

DELAWARE FALSE CLAIMS AND REPORTING ACT

100. Relator repeats and realleges the foregoing paragraphs of this Complaint.

101. This is a qui tam action brought by Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

102. 6 Del. C. § 1201(a) provides liability for any person who-

(1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or
(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

103. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebate) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program.

104. Astellas and Roche violated 31 Del. C. § 1005 by engaging in the conduct described herein.

105. Astellas and Roche furthermore violated 6 Del. C. § 1201(a) and knowingly caused false claims to be made, used and presented to the State of Delaware by its deliberate and systematic violation of federal and state laws, including the FCA, the Anti-Kickback Act, and 31 Del. C. § 1005 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

106. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, was unaware of Defendants' conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

107. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Astellas' and Roche's conduct. Compliance with applicable Delaware statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Delaware.

108. Had the State of Delaware known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

109. As a result of Astellas' and Roche's violation of 6 Del. C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

110. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of himself and the State of Delaware.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Delaware:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the State of Delaware;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 6 Del C. § 1205, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT IV.

FLORIDA FALSE CLAIMS ACT

111. Relator repeats and realleges the foregoing paragraphs of this Complaint.

112. This is a qui tam action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 et seq.

113. Fla. Stat. § 68.082(2) provides liability for any person who-

(a) knowingly presents or causes to be presented to an officer or employee of an agency a false or fraudulent claim for payment or approval;
(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency;
(c) conspires to submit a false or fraudulent claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

114. In addition, Fla. Stat. § 409.920 makes it a crime to:

(c) knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source;

* * *

(e) knowingly, solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

115. Fla. Stat. §456.054(2) also prohibits the offering, payment, solicitation, or receipt of a kickback to a healthcare provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

116. Astellas and Roche violated Fla. Stat. § 409.920(c) and (e) and §456.054(2) by engaging in the conduct described herein.

117. Astellas and Roche violated Fla. Stat. § 409.920(c) and (e) and §456.054(2) by engaging in the conduct described herein.

118. Astellas and Roche furthermore violated Fla. Stat. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by its

deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, Fla. Stat. § 409.920(c) and (e) and §456.054(2) and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

119. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, was unaware of Defendants' conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

120. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Astellas' and Roche's conduct. Compliance with applicable Florida statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Florida.

121. Had the State of Florida known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

122. As a result of Astellas' and Roche's violation of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

123. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of himself and the State of Florida.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Florida:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,500 and not more than $ 11,000 for each false claim which Defendant caused to be presented to the State of Florida;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action,
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT V.

GEORGIA FALSE MEDICAID CLAIMS ACT

124. Relator repeats and realleges the foregoing paragraphs of this Complaint.

125. This is a qui tam action brought by Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, O.C.G.A. §49-4-168(2008) et seq.

126. O.C.G.A. § 49-4-168.1(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
(3) conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

127. Astellas and Roche violated O.C.G.A. § 49-4-168 et seq. by engaging in the conduct described herein.

128. Astellas and Roche furthermore violated O.C.G.A. § 49-4-168 and knowingly caused false claims to be made, used and presented to the State of Georgia by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

129. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, was unaware of Defendant's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

130. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Astellas' and Roche's conduct. Compliance with applicable Georgia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Georgia.

131. Had the State of Georgia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

132. As a result of Astellas' and Roche's violation of O.C.G. A. § 49-4-168, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

133. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to O.C.G. A. § 49-4-168 on behalf of himself and the State of Georgia.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Georgia:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the State of Georgia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to O.C.G.A. § 49-4-168 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VI.

HAWAII FALSE CLAIMS ACT

134. Relator repeats and realleges the foregoing paragraphs of this Complaint.

135. This is a qui tam action brought by Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 et seq.

136. Haw. Rev. Stat. § 661-21(a) provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or

* * *

(8) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

137. Astellas and Roche violated Haw. Rev. Stat. §661-21(a) and knowingly caused false claims to be made, used and presented to the State of Hawaii by its deliberate and systematic violation of federal and state laws, including the FCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

138. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

139. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of Hawaii in connection with Astellas' and Roche's conduct. Compliance with applicable Hawaii statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Hawaii.

140. Had the State of Hawaii known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

141. As a result of Astellas' and Roche's violation of Haw. Rev. Stat § 661-21(a) the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

142. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev, Stat. § 661-25(a) on behalf of himself and the State of Hawaii.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Hawaii:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendant's illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Hawaii;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661 - 27 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT VII.

ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

143. Relator repeats and realleges the foregoing paragraphs of this Complaint.

144. This is a qui tam action brought by Relator on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 111. Comp. Stat. 175 et seq.

145. 740 111. Comp. Stat. 175/3(a) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

146. In addition, 305 111. Comp. Stat. 5/8 A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

147. Astellas and Roche violated 305 111. Comp. Stat. 5/8A-3(b) by engaging in the conduct described herein.

148. Astellas and Roche furthermore violated 740 111. Comp. Stat. 175/3(a) and knowingly caused false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, and the Illinois Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

149. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

150. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with

Astellas' and Roche's conduct. Compliance with applicable Illinois statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Illinois.

151. Had the State of Illinois known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

152. As a result of Astellas' and Roche's violation of 740 111. Comp. Stat. 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

153. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 111 Comp. Stat. 175/3(b) on behalf of himself and the State of Illinois.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Illinois:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the State of Illinois;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 740 111. Comp. Stat. 175/4(d) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT VIII.

INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

154. Relator repeats and realleges the foregoing paragraphs of this Complaint.

155. This is a qui tam action brought by Relator on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5 et seq. provides:

Sec. 2.(b) A person who knowingly or intentionally:

(1) presents a false claim to the state for payment or approval;
(2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
(3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
(4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
(5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
(6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
(7) conspires with another person to perform an act described in subdivisions (1) through (6); or
(8) causes or induces another person to perform an act described in subdivisions (1) through (6)...

156. In addition, Indiana Code 5-11-5.5 et seq. prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Indiana Medicaid program.

157. Astellas and Roche violated the Indiana Code 5-11-5.5 et seq. by engaging in the conduct described herein.

158. Astellas and Roche furthermore violated Indiana Code 5-11 -5.5 et seq. and knowingly caused false claims to be made, used and presented to the State of Indiana by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, and the Indiana Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

159. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

160. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Astellas' and Roche's conduct. Compliance with applicable Indiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Indiana.

161. Had the State of Indiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

162. As a result of Astellas' and Roche's violation of Indiana Code 5-11-5.5 et seq., the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

163. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Indiana Code 5-11-5.5 et seq. on behalf of himself and the State of Indiana.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Indiana:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendant's conduct;
(2) A Civil penalty of at least five thousand dollars ($5,000);
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Indiana Code 5-11-5.5 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT IX.

LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

164. Relator repeats and realleges the foregoing paragraphs of this Complaint.

165. This is a qui tam action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 46: 437.1 et seq.

166. La. Rev. Stat. 46: 438.3 provides-

(A) No person shall knowingly present or cause to be presented a false or fraudulent claim;
(B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;

(C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;

167. In addition, La. Rev. Stat. 46:43 8.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash of in kind, for furnishing healthcare goods or services paid for in whole or in part by the Louisiana medical assistance programs.

168. Astellas and Roche violated La. Rev. Stat. 46:438.2(A) by engaging in the conduct described herein.

169. Astellas Roche furthermore violated La. Rev. Stat. 46:43 8.3 and knowingly caused false claims to be made, used and presented to the State of Louisiana by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act and La. Rev. Stat. 456: 438.2(A), and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

170. The State of Louisiana, by and through the Louisiana Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

171. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Astellas' and Roche's conduct. Compliance with applicable Louisiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Louisiana.

172. Had the State of Louisiana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

173. As a result of Astellas' and Roche's violation of La. Rev. Stat. 46:438.3 the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

174. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. 46: 439.1(A) on behalf of himself and the State of Louisiana.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Louisiana:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendant's conduct;
(2) A civil penalty of up to $ 10,000 for each false claim which Defendant caused to be presented to the State of Louisiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT X.

MICHIGAN MEDICAID FALSE CLAIMS ACT

175. Relator repeats and realleges the foregoing paragraphs of this Complaint.

176. This is a qui tam action brought by Relator on behalf of the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid False Claims Act. MI ST Ch. 400.603 et seq.

177. 400.603 provides liability in pertinent part as follows:

> Sec. 3. (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for medicaid benefits;
> (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a medicaid benefit...

178. In addition, MI ST Ch. 400.604 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Michigan Medicaid program.

179. Astellas and Roche violated MI ST Ch. 400.603 et seq. by engaging in the conduct described herein.

180. Astellas and Roche furthermore violated, MI ST Ch. 400.603 et seq. and knowingly caused false claims to be made, used and presented to the State of Michigan by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

181. The State of Michigan, by and through the Michigan Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

182. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Michigan in connection with Astellas' and Roche's conduct. Compliance with applicable Michigan statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Michigan.

183. Had the State of Michigan known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

184. As a result of Astellas' and Roche's violation of MI ST Ch. 400.603 et seq. the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

185. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to MI ST Ch. 400.603 et seq. on behalf of himself and the State of Michigan.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Michigan:

(1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendant's conduct;

(2) A civil penalty equal to the full amount received for each false claim which Defendant caused to be presented to the State of Michigan;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to MI ST Ch. 400.603 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XI.

MONTANA FALSE CLAIMS ACT

MONT. CODE ANN. § 17-8-403(a)-(b)

186. Relator repeats and realleges the foregoing paragraphs of this Complaint.

187. This is a qui tam action brought by Relator on behalf of the State of Montana to recover treble damages and penalties under the Montana False Claims Act, Mont. Code Ann § 17-8-403(l)(a)-(b)

188. 17-8-403 provides liability for any person who:

(a) knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;
(b) knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;
(c) conspiring to defraud the governmental entity by getting false claim allowed or paid by the governmental entity.
(h) as a beneficiary of an inadvertent submission of a false claim to the governmental entity, subsequently discovering the falsity of the claim and failing to disclose the false claim to the governmental entity within -a reasonable time after discovery of the false claim.

189. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an

express condition of payment of claims submitted to the State of Montana in connection with Astellas' and Roche's conduct. Compliance with applicable Montana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Montana.

190. Had the State of Montana known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

191. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Astellas and Roche, paid and continues to pay the claims that would not be paid but for Defendants' conduct.

192. By reason of the Astellas' and Roche's the State of Montana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

193. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, by Astellas and Roche.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Montana:

(1) Not less than two times and not more than three times the amount of actual damages which the State of Montana has sustained as a result of Defendant's conduct;
(2) A civil penalty of up to $ 10,000 for each false claim which Defendant caused to be presented to the State of Montana;
(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Montana Code Ann. § 17-8-403 (1)(A)-(B). and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XII.

NEVADA FALSE CLAIMS ACT

194. Relator repeats and realleges the foregoing paragraphs of this Complaint.

195. This is a qui tam action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. § 357.010, et seq.

196. Nev. Rev. Stat. § 357.040(1) provides liability for any person who-

(a) knowingly presents or causes to be presented a false claim for payment or approval;
(b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;
(c) conspires to defraud by obtaining allowance or payment of a false claim;
***
(h) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

197. In addition, Nev. Rev. Stat. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

198. Astellas and Roche violated Nev. Rev. Stat. § 422.560 by engaging in the conduct described herein.

199. Astellas and Roche furthermore violated Nev. Rev. Stat.§ 357.040(1) and knowingly caused false claims to be made, used and presented to the State of Nevada by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act and Nev. Rev. Stat. § 422.560, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

200. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, was unaware of Defendants' conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

201. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Astellas' and Roche's conduct. Compliance with applicable Nevada statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Nevada.

202. Had the State of Nevada known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

203. As a result of Astellas' and Roche's violation of Nev. Rev. Stat. § 357.040(1) the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

204. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Nev. Rev. Stat. § 357.080(1) on behalf of himself and the State of Nevada.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Nevada:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $ 10,000 for each false claim which Defendant caused to be presented to the State of Nevada;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Nev. Rev. Stat. § 357.210 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIII.

THE NEW HAMPSHIRE HEALTH CARE FALSE CLAIMS ACT

205. Relator repeats and realleges the foregoing paragraphs of this Complaint.

206. This is a qui tam action brought by Relator on behalf of the State of New Hampshire to recover treble damages and civil penalties under the New Hampshire Health Care False Claims Law, N.H. Rev. Stat. Ann. §167:61-b et seq. provides:

Any person shall be liable who...

(a) knowingly presents, or causes to be presented, to an officer or employee of the department a false or fraudulent claim for payment or approval;

> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department;
> (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.
> ***
> (f) Is a beneficiary of an inadvertent submission of a false claim to the department, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the department within a reasonable time after discovery of the false claim.

207. In addition, N.H. Rev. Stat. Ann. prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the New Hampshire Medicaid program.

208. Astellas and Roche violated the N.H. Rev. Stat. Ann by engaging in the conduct described herein.

209. Astellas and Roche furthermore violated N.H. Rev. Stat. Ann. §167:61-b, and knowingly caused false claims to be made, used and presented to the State of New Hampshire by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, and the New Hampshire Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

210. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

211. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an

express condition of payment of claims submitted to the State of New Hampshire in connection with Astellas' and Roche's conduct. Compliance with applicable New Hampshire statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Hampshire.

212. Had the State of New Hampshire known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

213. As a result of Astellas' and Roche's violation of N.H. Rev. Stat. Ann. §167:61-b et seq., the State of New Hampshire has been damaged in an amount far in excess of millions of dollars exclusive of interest.

214. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.H. Rev.Stat. Ann. §167:61-b et seq. on behalf of himself and the State of New Hampshire.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of New Hampshire:

(1) Three times the amount of actual damages which the State of New Hampshire has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of New Hampshire;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.H. Rev. Stat. Ann § 167:61-b et seq. and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIV.
NEW JERSEY FALSE CLAIMS ACT

215. Relator repeats and realleges the foregoing paragraphs of this Complaint.

216. This is a qui tam action brought by Relator on behalf of the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 et seq. (2008) et seq.

217. N.J. Stat. § 2A:32C-3 provides liability for any person who:

(a) knowingly presents, or causes to be presented, to an employee, officer, or agent of the State or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.

218. In addition, Section 17 of P.L. 1968, c.413 (C.30:4D717) of the New Jersey False Claims Act prohibits the solicitation, offer or receipt of any remuneration, including any kickback, rebate or bribe in connection with the furnishing of items or services for which payment is or may be made in whole or in part under the New Jersey Medicaid program.

219. Astellas and Roche violated Section 17 of P.L. 1968, c.413 (C.30:4D-17) by engaging in the conduct described herein.

220. Astellas and Roche furthermore violated N.J. Stat. § 2A:32C-1 et seq. and knowingly caused false claims to be made, used and presented to the State of New Jersey by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, and the New Jersey False Claims Act and Kickback statute, and by virtue of the

fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

221. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

222. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Jersey in connection with Astellas' and Roche's conduct. Compliance with applicable New Jersey statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Jersey.

223. Had the State of New Jersey known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

224. As a result of Astellas' and Roche's violation of N.J. Stat. § 2A:32C-1 et seq., the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

225. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.J. Stat. § 2A:32C-1 et seq. on behalf of himself and the State of New Jersey.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of New Jersey:

(1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C. s.3729 et seq.) which Defendant caused to be presented to the State of New Jersey;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.J. Stat. § 2A:32C-1 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XV.

NEW MEXICO MEDICAID FALSE CLAIMS ACT AND NEW MEXICO FRAUD AGAINST TAXPAYERS ACT

226. Relator repeats and realleges the foregoing paragraphs of this Complaint.

227. This is a qui tam action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Medicaid False Claims Act N.M. Stat. Ann§§ 27-14-1 et seq.

228. Section 4 provides liability in pertinent part as follows:

A person ...shall be liable...if the person:

A. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that such claim is false or fraudulent;
B. presents, or causes to be presented, to the state a claim for payment under the medicaid program knowing that the person receiving a medicaid benefit or payment is not authorized or is not eligible for a benefit under the medicaid program;
C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the medicaid program paid

for or approved by the state knowing such record or statement is false;

D. conspires to defraud the state by getting a claim allowed or paid. Under the medicaid program knowing that such claim is false or fraudulent.

229. It is also brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann § 44-9-1 et seq. provides liability in pertinent part as follows:

230. § 44-9-3(A) A person shall not:

(1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee or other recipient of state funds a false or fraudulent claim for payment or approval;

(2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim;

(3) conspire to defraud the state by obtaining approval or payment on a false or fraudulent claim.

231. In addition, N.M, Stat. Ann§ § 30-44-7 et seq. prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the New Mexico Medicaid program.

232. Astellas and Roche violated N.M. Stat. Ann§§ 30-44-7 et seq. by engaging in the conduct described herein.

233. Astellas and Roche furthermore violated, N.M. Stat. Ann§§ 27-14-1 et seq. and knowingly caused false claims to be made, used and presented to the State of New Mexico by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in

connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

234. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

235. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Mexico in connection with Astellas' and Roche's conduct.

236. Compliance with applicable New Mexico statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Mexico.

237. Had the State of New Mexico known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by. healthcare providers and third party payers in connection with that conduct.

238. As a result of Astellas' and Roche's violation of N.M. Stat. Ann§§ 27-14-1 et seq. the State of New Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

239. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.M. Stat. Ann§§ 27-14-1 et seq. on behalf of himself and the State of New Mexico.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of New Mexico:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of New Mexico;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.M. Stat. Ann§§ 27-14-1 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVI.

NEW YORK FALSE CLAIMS ACT

240. Relator repeats and realleges the foregoing paragraphs of this Complaint.

241. This is a qui tam action brought by Relator on behalf of the State of New York to recover treble damages and civil penalties under the New York False Claims Act, 2007 N. Y. Laws 58, Section 39, Article XIII.

242. Section 189 provides liability for any person who:

1.(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or local government, a false or fraudulent claim for payment or approval;
1.(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or local government;
1.(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

243. In addition, the New York State Consolidated Laws prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the New York Medicaid program.

244. Astellas and Roche violated the New York State Consolidated Laws by engaging in the conduct described herein.

245. Astellas and Roche furthermore violated, 2007 N.Y. Laws 58, Section 39, Article XIII, and knowingly caused false claims to be made, used and presented to the State of New York by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, and the New York Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

246. The State of New York, by and through the New York Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

247. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with Astellas' and Roche's conduct. Compliance with applicable New York statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New York.

248. Had the State of New York known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy

of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

249. As a result of Astellas' and Roche's violation of 2007 N. Y. Laws 58, Section 39, Article XIII, the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

250. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 2007 N. Y. Laws 58, Section 39, Article XIII, on behalf of himself and the State of New York.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of New York:

(1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $6,000 and not more than $12,000 for each false claim which Defendant caused to be presented to the State of New York;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 2007 N. Y. Laws 58, Section 39, Article XIII, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVII.

OKLAHOMA MEDICAID FALSE CLAIMS ACT

251. Relator repeats and realleges the foregoing paragraphs of this Complaint.

252. This is a qui tam action brought by Relator on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act 63 Okl. St. §5053 (2008) et seq.

253. 63 Okl. St. § 5053.1 (2)(B) provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

254. In addition, 56 Okl. St. § 1005 (2008) of the Oklahoma Medicaid Program Integrity Act prohibits the solicitation or receipt of any benefit, pecuniary benefit, or kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid Program.

255. In addition, 56 Okl. St. § 1005 (2008) of the Oklahoma Medicaid Program Integrity Act prohibits the solicitation or receipt of any benefit, pecuniary benefit, or kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid Program.

256. Astellas and Roche violated 56 Okl. St. § 1005 et seq. by engaging in the conduct described herein.

257. Astellas and Roche furthermore violated 63 Okl. St. § 5053.1 et seq. and knowingly caused false claims to be made, used and presented to the State of Oklahoma by its

deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, and the Oklahoma Medicaid Program Integrity Act and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

258. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

259. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Astellas' and Roche's conduct. Compliance with applicable Oklahoma statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Oklahoma.

260. Had the State of Oklahoma known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

261. As a result of Astellas' and Roche's violation of 63 Okl. St. § 5053.1 et seq., the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

262. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 63 Okl. St. § 5053.1 et seq. on behalf of himself and the State of Oklahoma.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Oklahoma:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Oklahoma;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 63 Okl. St. § 5053.1 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVIII.

RHODE ISLAND STATE FALSE CLAIMS ACT

263. Relator repeats and realleges the foregoing paragraphs of this Complaint.

264. This is a qui tam action brought by Relator on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island State False Claims Act R.I. Gen. Laws §9-1.1-1 (2008) et seq.

265. R.I. Gen. Laws § 9-1.1-3 provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

266. In addition, R.I. Gen. Laws § 40-8.2-3(2)(i) prohibits the solicitation, receipt, offer or payment of any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Rhode Island Medicaid program.

267. Astellas and Roche violated R.I. Gen. Laws § 40-8.2-3 et seq. by engaging in the conduct described herein.

268. Astellas and Roche furthermore violated R.I. Gen. Laws § 9-1.1-1 and knowingly caused false claims to be made, used and presented to the State of Rhode Island by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, and the Rhode Island General Laws and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

269. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

270. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Rhode Island in connection with Astellas' and Roche's conduct. Compliance with applicable Rhode Island statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Rhode Island.

271. Had the State of Rhode Island known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and

efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

272. As a result of Astellas' and Roche's violation of R.I. Gen. Laws §9-1.1-1, the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

273. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to R.I. Gen. Laws §9-1.1-1 et seq. on behalf of himself and the State of Rhode Island.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Rhode Island:

(1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Rhode Island;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to R.I. Gen. Laws §9-1.1-4(d) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIX.

TENNESSEE FALSE CLAIMS ACT

274. Relator repeats and realleges the foregoing paragraphs of this Complaint.

275. This is a qui tam action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 et seq. and Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 et seq.

276. § 4-18-103(a) provides liability for any person who-

(1) Knowingly presents, or causes to be presented to an officer or employee of the state..., a false claim for payment or approval;
(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
(3) Conspires to defraud the state or any political subdivision by getting a claim allowed or paid by the state of by any political subdivision.

277. § 71-5-182(a)(1) provides liability for any person who-

(A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
(B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
(C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

278. Astellas and Roche violated Tenn. Code Ann. § 4-18-103(a) and § 71-5-1 82(a)(1) and knowingly caused false claims to be made, used and presented to the State of Tennessee by its deliberate and systematic violation of federal and state laws, including the FCA and Anti-Kickback Act, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

279. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

280. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Astellas' and Roche's conduct. Compliance with applicable Tennessee statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Tennessee.

281. Had the State of Tennessee known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

282. As a result of Astellas' and Roche's violation of Term. Code Ann. § 4-18-103(a) and § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

283. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 4-18 - 103 (a) and § 71-5-183(a)(l) on behalf of himself and the State of Tennessee.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Tennessee:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendant's conduct;

(2) A civil penalty of not less than $2,500 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Tennessee;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71 -5-183 (c) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XX.

TEXAS MEDICAID FRAUD PREVENTION LAW

284. Relator repeats and realleges the foregoing paragraphs of this Complaint.

285. This is a qui tam action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under Tex. Hum. Res. Code § 36.001 et seq.

286. Tex. Hum. Res. Code § 36.002 provides liability for any person who-

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:
(a) on an application for a contract, benefit, or payment under the Medicaid program; or
(b) that is intended to be used to determine its eligibility for a benefit
(2) knowingly or intentionally concealing or failing to disclose an event:
(A) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of.
(i) the person, or
(ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
(B) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;
***
(4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

> ***
> (B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;
> (5) ... knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

287. Astellas and Roche violated Tex. Hum. Res. Code § 36.002 and knowingly caused false claims to be made, used and presented to the State of Texas by its deliberate and systematic violation of federal and state laws, including the FDC A, federal Anti-kickback Act and § 36.002, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

288. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

289. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Astellas' and Roche's conduct. Compliance with applicable Texas statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Texas.

290. Had the State of Texas known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of

Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

291. As a result of Astellas' and Roche's violation of Tex. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

292. Astellas and Roche did not, within 30 days after it first obtained information as to such violation, furnish such information to officials of the State responsible for investigating false claims violation, did not otherwise fully cooperate with any investigation of the violation, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

293. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tex. Hum. Res. Code § 36.101 on behalf of himself and the State of Texas.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Texas:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 or more than $ 15,000 pursuant to Tex. Hum.. Res. Code § 36.025(a)(3) for each false claim which Defendant cause to be presented to the state of Texas;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tex. Hum. Res. Code §36.110, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXI.

WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT

294. Relator repeats and realleges the foregoing paragraphs of this Complaint.

295. This is a qui tam action brought by Relator on behalf of the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 et seq.

296. Wis. Stat. § 20.931 (2) provides liability for any person who:

(a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.

(c) conspires to defraud this State by obtaining allowance or payment of claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance Program;

***

(g) knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance Program.

297. In addition, Wis. Stat. § 49.49(2) of the Wisconsin Public Assistance Code prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Wisconsin Medicaid program.

298. Astellas and Roche violated Wis. Stat. § 49.49(2) by engaging in the conduct described herein.

299. Astellas and Roche furthermore violated Wis. Stat. § 20.931 et seq. and knowingly caused false claims to be made, used and presented to the State of Wisconsin by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, and the Wisconsin Public Assistance Code and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

300. The State of Wisconsin, by and through the Wisconsin Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

301. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Wisconsin in connection with Astellas' and Roche's conduct. Compliance with applicable Wisconsin statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Wisconsin.

302. Had the State of Wisconsin known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

303. As a result of Mycamine's violation of Wis. Stat. § 20.931 et seq., the State of Wisconsin has been damaged in an amount far in excess of millions of dollars exclusive of interest.

304. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Wis. Stat. § 20.931 et seq. on behalf of himself and the State of Wisconsin.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the State of Wisconsin:

(1) Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the State of Wisconsin;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Wis. Stat. § 20.931 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXII.

MASSACHUSETTS FALSE CLAIMS ACT

305. Relator repeats and realleges the foregoing paragraphs of this Complaint.

306. This is a qui tam action brought by Relator on behalf of the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Chap. 12 § 5(A) et seq.

307. Mass. Gen. Laws Chap. 12 § 5B provides liability for any person who-

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
> ***
> (9) is a beneficiary of an inadvertent submission of a false claim . to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim shall be liable to the commonwealth or political subdivision.

308. In addition, Mass. Gen. Laws Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

309. Astellas and Roche violated Mass. Gen. Laws Chap. 118E § 41 by engaging in the conduct described herein.

310. Astellas and Roche furthermore violated Mass. Gen. Laws Chap. 12 § 5B and knowingly caused false claims to be made, used and presented to the Commonwealth of Massachusetts by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, Mass. Gen. Law Chap. 118E § 41 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

311. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

312. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief: also an express condition of payment of claims submitted to the Commonwealth of Massachusetts in connection with Astellas' and Roche's conduct. Compliance with applicable Massachusetts statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Massachusetts.

313. Had the Commonwealth of Massachusetts known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

314. As a result of Astellas' and Roche's violation of Mass. Gen. Laws Chap. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

315. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mass. Gen. Laws Chap. 12 § 5(c)(2) on behalf of himself and the Commonwealth of Massachusetts.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the Commonwealth of Massachusetts:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the Commonwealth of Massachusetts;

(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Chap. 12, §5F and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIII.

VIRGINIA FRAUD AGAINST TAXPAYERS ACT

316. Relator repeats and realleges the foregoing paragraphs of this Complaint.

317. This is a qui tam action brought by Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Va. Code Ann. § 8.01-216.3a provides liability for any person who:

1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;
3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid.

318. In addition, Va. Code Ann. § 32.1 -315 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Virginia Medicaid program.

319. Astellas and Roche violated Va.Code Ann. §32.1-315 by engaging in the conduct described herein.

320. Astellas and Roche furthermore violated Va. Code Ann. §§8.01-216.3a and knowingly caused false claims to be made, used and presented to the Commonwealth of Virginia by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, VA Code ANN §32.1-315 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

321. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

322. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Astellas' and Roche's conduct. Compliance with applicable Virginia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Virginia.

323. Had the Commonwealth of Virginia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

324. As a result of Astellas' and Roche's violation of Va. Code Ann. §8.01-216.3(a), the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

325. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Va. Code Ann. § 8.01-216.5 on behalf of himself and the Commonwealth of Virginia.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the Commonwealth of Virginia:

(1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendant's conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to the Commonwealth of Virginia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Va. Code Ann. § 8.01-216.7 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIV.

DISTRICT OF COLUMBIA PROCUREMENT

REFORM AMENDMENT ACT

326. Relator repeats and realleges the foregoing paragraphs of this Complaint.

327. This is a qui tam action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 et seq.

328. D.C. Code § 2-308.14(a) provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
(2) knowingly makes, uses, or causes to: be made or used, a false record or statement to get a false claim paid or approved by the District;
(3) conspires to defraud the District by getting a false claim allowed or paid by the District;
***
(8) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

329. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

(1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program, or
(2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

330. Astellas and Roche violated D.C. Code § 4-802(c) by engaging in the illegal conduct described herein.

331. Astellas and Roche furthermore violated D.C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act D.C. Code § 4-802(c), and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the government-funded healthcare programs.

332. The District of Columbia, by and through the District of Columbia Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's illegal conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

333. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the District of Columbia in connection with Astellas' and Roche's illegal conduct. Compliance with applicable D.C. statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the District of Columbia.

334. Had the District of Columbia known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

335. As a result of Astellas' and Roche's violation of D.C. Code § 2-308,14(a) the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

336. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of himself and the District of Columbia.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the District of Columbia:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendant's illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the District of Columbia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXV.

CONNECTICUT FALSE CLAIMS ACT

337. Relator repeats and realleges the foregoing paragraphs of this Complaint.

338. This is a qui tam action brought by Relator and the State of Connecticut to recover treble damages and civil penalties under the Connecticut Medical Assistance Program False Claims Act, § 17b-301a et. seq. (the "Act").

339. The Act provides liability for any person who (1) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval under the medical assistance programs administered by the Department of Social Services; (2) knowingly makes, uses or causes to be made or used a false record or statement to secure the payment or approval by the state of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services; (3) conspires to defraud the state by securing the allowance or payment of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services.

340. Astellas and Roche violated Conn. Code § 17b-301b by engaging in the illegal conduct described herein and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the Government Health Care Programs.

341. In addition, Conn. Code § 53a-161d, prohibits knowingly offering or paying any benefit with intent to influence such person for the furnishing of any goods, facilities or services for which a claim for benefits or reimbursement has been filed with a local state or federal agency.

342. Astellas and Roche violated Conn. Code § 53a-161d by engaging in the conduct described herein.

343. Astellas and Roche furthermore violated Conn. Code § 17b-301b and knowingly caused false claims to be made, used and presented to the State of Connecticut by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, Conn. Code § 53a-161d and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Health Care Programs.

344. Connecticut, by and through the Connecticut Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's illegal conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

345. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to Connecticut in connection with Astellas' and Roche's illegal conduct. Compliance with applicable Connecticut statutes, regulations and Pharmacy Manuals was also an express condition for payment of claims submitted to Connecticut.

346. Had the State of Connecticut known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and

efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

347. As a result of Astellas' and Roche's violation of Conn. Code § 17b-301b, Connecticut has been damaged in an amount far in excess of millions of dollars exclusive of interest.

348. Relator is a private citizen with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Connecticut Code § 17b-301d on behalf of himself and the State of Connecticut.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To Connecticut:

(1) Three times the amount of actual damages which Connecticut has sustained as a result of Defendant's illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to Connecticut;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Conn. Code § 17b-301e and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVI.

MINNESOTA FALSE CLAIMS ACT

349. Relator repeats and realleges the foregoing paragraphs of this Complaint.

350. This is a qui tam action brought by Relator and the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, § 15C.01 et seq. (the "Act").

351. The Act provides liability for any person who (1) knowingly presents or causes to be presented, to an officer or employee of the state or a political subdivision a false or fraudulent claim for payment or approval; (2) knowingly makes or uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a political subdivision; (3) knowingly conspires to either present a false or fraudulent claim to the state or a political subdivision for payment or approval or makes, uses, or causes to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim.

352. Astellas and Roche violated Minnesota Statute § 15C.02 by engaging in the illegal conduct described herein and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the Government Health Care Programs.

353. In addition, Minnesota Statute § 62J.23 provides that the restrictions in the federal Medicare anti-kickback statutes apply to all persons in the state.

354. Astellas and Roche furthermore violated Minn Stat. § 15C.02 and knowingly caused false claims to be made, used and presented to the State of Minnesota by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, Minn. Stat. § 15C.02 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Health Care Programs.

355. Minnesota, by and through the Minnesota Medicaid program and other state healthcare programs, was unaware of Astellas' and Roche's illegal conduct and paid the claims submitted by healthcare providers and third party payers in connection therewith.

356. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to Minnesota in connection with Astellas' and Roche's illegal conduct. Compliance with applicable Minnesota statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to Minnesota.

357. Had the State of Minnesota known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

358. As a result of Astellas' and Roche's violation of Minn. Stat. § 15C.02, Minnesota has been damaged in an amount far in excess of millions of dollars exclusive of interest.

359. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Minn. Stat § 15C.05 on behalf of himself and the State of Minnesota.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To Minnesota:

(1) Three times the amount of actual damages which Minnesota has sustained as a result of Defendant's illegal conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendant caused to be presented to Connecticut;

(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Minn. Stat. § 15C.13 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorney's fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVII.

CHICAGO FALSE CLAIMS ACT

360. Relator repeats and realleges the foregoing paragraphs of this Complaint.

361. This is a qui tam action brought by Relator and the City of Chicago to recover treble damages and civil penalties under the Chicago False Claims Act, § 1-22-010 et seq.

362. The Municipal Code of Chicago § 1-22-020 provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the City a false or fraudulent claim for payment or approval;
(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the City;
(c) conspires to defraud the City by getting a false or fraudulent claim allowed or paid by the City.

363. Astellas and Roche violated the Municipal Code of Chicago § 1-22-020 and knowingly caused thousands of false claims to be made, used and presented to the City of Chicago by its deliberate and systematic violation of federal and state laws, including the FCA, federal Anti-Kickback Act, Municipal Code of Chicago § 1-22-020, and by virtue of the fact that

none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the government-funded healthcare programs.

364. The City of Chicago, unaware of Astellas' and Roche's illegal conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

365. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the City of Chicago in connection with Astellas' and Roche's illegal conduct. Compliance with applicable Chicago statutes and regulations was also an express condition of payment of claims submitted to the City of Chicago.

366. Had the City of Chicago known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the Mycamine in the pediatric population, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

367. As a result of Astellas' and Roche's violation of Chicago's Municipal Code § 1-22-020, the City of Chicago has been damaged in an amount far in excess of millions of dollars exclusive of interest.

368. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Municipal Code of Chicago § 1-22-030 on behalf of himself and the City of Chicago.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Astellas and Roche:

To the City of Chicago:

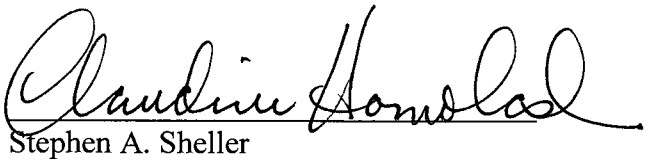
(1) Three times the amount of actual damages which the City of Chicago has sustained as a result of Defendant's illegal conduct;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendant caused to be presented to the City of Chicago;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to the Municipal Code of Chicago § 1-22-030(d) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable-and just.

Respectfully submitted,



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Dated: 3-8-2010

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